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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,199	05/18/2000	Rodney Alan Jue	SCIOS.010CP1	9828

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EXAMINER

SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-74 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-74 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Part III: Detailed Office Action

Notice: Effective June 18, 2000, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.

Restriction Requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-27 and 28-34, as they are drawn to VEGF dimers wherein Cys₁₁₆ is bound to an extraneous cysteine, classified in class 530, subclass 408.
- II. Claims 28-34, as they are drawn to disulfide linked VEGF dimers, classified in class 530, subclass 399.
- III. Claims 28-34, as they are drawn to VEGF dimers wherein Cys₁₁₆ is unbound, classified in class 530, subclass 407.
- IV. Claims 35-67, drawn to recombinant production of VEGF dimers, classified in class 435, subclass 69.1.
- V. Claims 68-70, 72 and 74, drawn to methods of stimulating vascular growth, classified in class 424, subclass 198.1.
- VI. Claim 71, drawn to a methods of treating essential hypertension, classified in class 424, subclass 198.1.
- VII. Claim 73, drawn to a methods of treating polycystic kidney disease, classified in class 424, subclass 198.1.

The inventions are distinct, each from the other because:

Inventions I-III are drawn to physically, functionally and patentably distinct products wherein each product does not require the others, the products have different means of manufacture, and the products require non-coextensive searches. For example, although VEGF is common to all three inventions, VEGF itself is not an advance over the prior art, the each invention requires a search of

the particular modification that is made, which searches are non-overlapping. Accordingly, restriction is proper.

Invention IV is to each of Inventions I-III as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed
5 can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products may be made non-recombinantly by isolation from the natural source with appropriate modification.

The claims of Inventions V-VII are improper dependent claims, as claim 35 is drawn to a
10 process, and not a composition. However, the claims *may* be related to the products of Inventions I-III as products (Inventions I-III and processes of use (Inventions V-VII). The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In
15 the instant case the products may be used in *in vitro* cell culture or assays.

Inventions V-VII are drawn to patentably distinct methods. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

20 Invention IV has substantively different process steps, beginning and ending points from Inventions V-VII, and require non-coextensive searches.

Inventions V-VII, although drawn to the use of a common product, are nonetheless patentably distinct because that common product is being used to achieve different means and effects, and the search for the respective methods is drawn to art relating to the desired effect, and is thus not
25 coextensive.

Therefore, a search and examination of all Invention IV-VII's methods in one patent application would result in an undue burden, since the searches for the Invention IV-VII's

methods are not co-extensive, the classification is different, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Election of Species:

In addition to the above restriction requirement, several species elections are required, as follows:

10 **A) If one of Inventions I-IV is elected:**

This application contains claims directed to the following patentably distinct species of the claimed invention: VEGF comprising residues 4-116 of SEQ ID NO: 1, VEGF comprising residues 1-120 of SEQ ID NO: 1, VEGF comprising residues 1-121 of SEQ ID NO: 1 and VEGF comprising residues 5-120 of SEQ ID NO: 1.

15 Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4, 12-17, 22-28 and 32-34 are generic to Invention I, claims 28 and 32-34 are generic to Invention II and Invention III, and claims 35, 38--39, 41-67 are generic to Invention IV.

20 Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

25 Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant

should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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B) Additionally, if Invention IV is elected:

Claims 35-67 are generic to a plurality of disclosed patentably distinct species comprising (i) VEGF dimers wherein Cys₁₁₆ is bound to an extraneous cysteine, (ii) disulfide linked VEGF dimers and (iii) VEGF dimers wherein Cys₁₁₆ is unbound. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

10

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Advisory Information:

To be fully responsive to this Office Action, applicant must clearly elect a single group from restriction groups I-VII above, and must additionally make appropriate elections of species, as outlined in (A) and (B) above. Applicants are further required to clearly point out which claims correspond to the elected invention and species. Should applicants elect one of inventions V-VII, they are further advised to amend the dependency of the elected claims accordingly, in the interest of compact prosecution.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

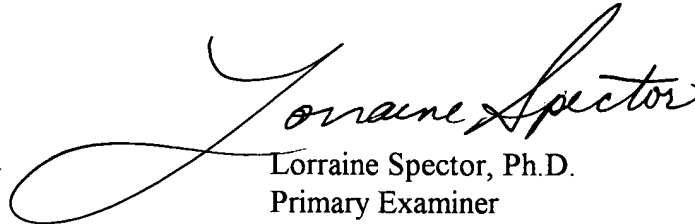
Serial Number 09/575199

Art Unit 1647

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Spector via telephone number 703-746-5228. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.


Lorraine Spector, Ph.D.
Primary Examiner

LMS
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1/24/02